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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/558,260	04/25/2000	David W. Cunningham		8995

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EXAMINER

PORTER, RACHEL L

ART UNIT PAPER NUMBER

3626

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/558,260		CUNNINGHAM, DAVID W.	
	Examiner		Art Unit	
	Rachel L. Porter		3626	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10 is/are allowed.
- 6) ☒ Claim(s) 11-14 and 16-28 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 5/22/03. Claims 1-28 are pending. Claims 1,2,3,7,8 and 15 have been amended. Claims 17-28 are new.
2. The information disclosure statement filed June 23, 2000 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language (German Document No. DE431194A1). It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

3. The rejection of claims 2, 3,7,8 and 15 under 35 U.S.C. 112, second paragraph, is hereby withdrawn due to the amendment filed 5/22/03.

Double Patenting

4. The obviousness-type double patenting rejections raised in the previous Office Action (Paper No. 3) are hereby withdrawn in view of the Terminal Disclaimer filed 5/27/03.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11,13 and 16-22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case of claim 11, the recited steps of merely creating pharmaceutical product media, issuing the media, "activating" the media by transferring prescription information to the media, and presenting the media to obtain a prescribed medication does not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper. These steps only constitute an idea of how to obtain prescribed medicine using a standard (e.g. written) prescription.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention produces a pharmaceutical product media (i.e., repeatable) used in obtaining a prescribed medication (i.e., useful and tangible).

Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claim 11 is deemed to be directed to non-statutory subject matter.

Similarly, claims 13 and 16-22 are dependent from claim 11 and do not include steps that apply, involve, use, or advance the technological arts. As such these claims are also rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter.

Allowable Subject Matter

6. Claims 1-10 are allowed.
7. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
8. The following is a statement of reasons for the indication of allowable subject matter: Claims 1 and 15 are drawn toward a method of activating and validating pharmaceutical product media by communicatively linking the media to a central computing station. The closest prior art of record does not teach or fairly suggest the combined steps of: 1) activating the pharmaceutical product media prior to issuing the media to a patient, wherein the activation by the prescriber includes the prescriber

communicatively linking the media to a central computing station which records encoded information from the media into a database associated with the central computing station; and 2) validating the product media, wherein validation by the pharmacy includes communicatively linking the presented pharmaceutical product media with the central computing station to determine if the pharmaceutical product media has been activated by a prescriber. Dependent claims 2-8 incorporate the allowable features of claim 1 and are equally allowable.

Similarly, claim 9 is drawn toward a system, which controls and tracks the transfer of pharmaceutical product media and the pharmaceutical product. The closest prior art of record does not disclose: prescriber terminals and pharmacy terminals receiving and reading data encoded on pharmaceutical product media and communicating that data to the central computing station to track and control the movement of pharmaceutical product media and the dispensing of a pharmaceutical product identified by the individual pharmaceutical product media. Dependent claim 10 incorporates the allowable features of claim 9 and is equally allowable.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Claim 11,13, 16-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lapsker (USPN 4,971,362).

Claim 11) Lapsker teaches a method of prescribing and dispensing prescription pharmaceutical products comprising:

- forming a pharmaceutical product media and encoding that media with information that identifies one or more particular prescription pharmaceutical products (Lapsker: col. 4, lines 10-45)
- issuing the pharmaceutical product media to one or more prescribers;(col. 4, lines 10-49)
- activating the pharmaceutical media and transferring the activated pharmaceutical product media from the prescriber to the patient, wherein the activated pharmaceutical product media identifies one or more prescription pharmaceutical products that have been prescribed by the prescriber for the patient; and (Lapsker: col. 4, lines 50-59; col. 5, lines 46-53)
- presenting the activated pharmaceutical product media to a pharmacy that fills the prescription identified by the pharmaceutical product media (Lapsker: col. 6, lines 14-32)

Claim 13) Lapsker teaches the method of claim 11 wherein the pharmacy validates the media prior to fulfilling the prescription identified thereby. (Lapsker: col. 6, lines 14-31)

Claim 16) Lapsker teaches the method of claim 11, wherein the pharmaceutical product media includes a plurality of data fields, including at least one data field for

identifying at least one prescribed pharmaceutical product, and associated data fields for identifying the quantity and number of refills for the associated prescribed pharmaceutical product. (col. 4, line 39-col. 5, line 2; col. 5, lines 47-61)

Claims 17-18) Lapsker teaches a method wherein the issuing and activation of the media are carried out in separate steps and wherein the steps of issuing, activating, transferring and presenting are carried out in the order set forth. (col. 4, line 11- col. 6, line 32)

Claim 19) Lapsker teaches a method wherein presenting the pharmaceutical product media to the pharmacy and the dispensing of the identified product is conditioned upon the prior activation of the media. (col. 4, lines 46-67; col. 6, lines 14-33)

(Claim 20) Lapsker teaches a method wherein activating the pharmaceutical product media is conditioned upon the prior issuance of the media. (col. 4, lines 50-59; col. 5, lines 11-27)

Claims 21-22) Lapsker teaches a method wherein the media is issued in an inactive state (i.e. without a signature), and wherein in activating the product media it is converted from an inactive to an active state. (col. 4, line 11- col. 6, line 32) Moreover, it is respectfully submitted that the drug dispensary (i.e. pharmacy) must note the signature of the prescribing physician on the prescription leaf and cheque before dispensing the drug. As such, the presenter must present the media in its "activated state" (i.e. with a prescriber's signature) in order to receive the desired drug.

Claim 23) Lapsker teaches a method of claim 11 including storing selected information on the pharmaceutical product media in a database. (col. 6, lines 28-33)

The pharmacist stores a copy of the prescription portion of the media in his/her records (i.e. database).

Claim 24) Lapsker teaches a method including recording in the database that a particular media has been activated. (col. 6, lines 11-33) The stored prescription includes the signature of the physician. (i.e. activation of the media)

Claim 25) Lapsker teaches method of claim 24 further including recording information in the database that indicates that the product media has been presented to a pharmacy and that the pharmacy has delivered the pharmaceutical product identified on the media presented. (col. 5, lines 15-36; col. 6, lines 14-41)

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 12,14 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lapsker (USPN 4,971,362) in view of Edelson et al (USPN 5,737,539).

Claim 12 and 14) Lapsker teaches the method of claim 11 further comprising the activation and validation of pharmaceutical product media. (col. 4, lines 50-59; col. 6, lines 14-32) Lapsker further discloses a method wherein a database records if the presented pharmaceutical product media has been appropriately issued by a prescriber.

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(col. 5, lines 3-6; col. 6, lines 14-32—Prescription includes practitioner's identification code. Pharmacist must make note of prescription information and sign that it has been dispensed). However, Lapsker does not expressly disclose a prescriber communicatively linking the pharmaceutical product media to a central computing station which records the information from the media into a database associated with the central computing station. Lapsker also does not disclose that the media is validated by communicatively linking the presented pharmaceutical product media with a central computing station to determine if the media has been appropriately issued. Edelson teaches the use of a central computing station (Figure 16; col. 46, line 10-col. 47, line 36) and communication links to store and access patient-specific prescription data. Edelson further discloses a method that provides a database associated with the central computing station to record prescription entry and prescription fulfillment information. Moreover this database is accessible to prescribers and pharmacists. (col. 26, line 55-col. 28, line 7). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lapsker with the teachings of Edelson to record information regarding the status of prescriptions in a database accessible to prescribers and pharmacies and to use the database to validate that a product media (i.e. prescription) has been properly issued by a prescriber. As suggested by Edelson, one would have been motivated to do this to minimize prescription fraud and system abuse. (col. 27, line 30-43)

Claims 26-28) Lapsker teaches the method of claim 11 including recording information relative to the product media in a database. (col. 6, lines 28-33) Lapsker

also discloses that the step of activating includes identifying the product media that the prescriber wants to activate and storing this information in a database. (i.e. the pharmacist's records) (col. 4, line 50-54; col. 5, lines 8-15). Lapsker further discloses that the pharmacist's database records that a particular product identified on the product media has been delivered to the person. (col. 5, lines 28-33; col. 6, lines 32). However, Lapsker does not expressly disclose that the database is a database that has communication links to a series of prescribers and a series of pharmacies. Edelson discloses a method that provides a database that records prescription entry and prescription fulfillment information and is accessible to a series of prescribers (i.e. point-of care) and to a series of pharmacies. (col. 26, line 55-col. 28, line 7). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lapsker with the teachings of Edelson to record information regarding the status of prescriptions in a database accessible to prescribers and pharmacies. As suggested by Edelson, one would have been motivated to do this to ensure that prescriptions have not been filled multiple times and thereby avoid system abuse. (col. 27, line 30-43)

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Ukens ("Cognitive Services: Pharmacy's New Hope) discloses the use of "smart cards" to store a patient's prescription information.

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- Rose et al (USPN 4,695,954) discloses a system that requires the patient to present a pharmaceutical product media to receive prescribed medication dosages.
- Bertina et al (USPN 5,682,027) teaches the use of intelligent pharmaceutical product media (i.e. IC cards) for prescription dispensing.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is 703-305-0108. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703)305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1113.

RP
RP

August 11, 2003


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
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